K121611

4 510(K) SUMMARY

AUG 23 2012

Submitter: AGA Medical Corporation
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Date Prepared: May 31, 2012

Trade Name: AMPLATZER® TorqVue® FX Delivery Systems

Common Name: Catheter Delivery System

Classification: Class II, 21 CFR 870.1250
Catheter, Percutaneous

Product Code: DQY

Predicate Device(s): AMPLATZER® TorqVue® (45°) Delivery System (K072313)
AMPLATZER® TorqVue® 45°x45° Delivery Sheath (K083214)

Device Description: The AMPLATZER® TorqVue® FX Delivery Systems (also referred to herein as ITV FX) are general purpose delivery systems designed to provide a pathway through which devices are introduced within the chambers of the heart. The ITV FX Delivery Systems are an extension of the AMPLATZER TorqVue (ITV) Delivery System product line.

The technological characteristics of the ITV FX are the same as the predicate devices, with the following differences:

- The TorqVue FX Delivery System contains a flex delivery cable assembly that incorporates a nitinol core wire surrounded by a stainless steel coil capped by a hub and a self-sealing hemostasis valve. The flex cable assembly provides rigidity for advancing devices through the sheath and allows the core wire to be extended out of the coil to provide flexibility for confirming correct placement of the deployed device.
- The TorqVue FX Delivery System contains an 0.035" compatible extension wire, which is only used for attaching to the delivery cable *in vivo* when there is a need to replace the sheath with a larger sheath. The standard ITV and ITV FX dilators fit over the extension wire and delivery cable core wire.

The ITV FX Delivery System sheath will be offered with a 45° curve with a 60-cm useable length (6Fr, 7Fr, 8Fr) or 80-cm usable length (7Fr, 8Fr, 9Fr, 10Fr, 12Fr, 13Fr) and will be recommended for use with a subset of the AMPLATZER occluders that currently recommend the TorqVue (45°) Delivery Systems.

The ITV FX Delivery System includes a delivery sheath, dilator, delivery cable, extension wire, loader, delivery cable vise, two hemostasis valves, and for the 10, 12 and 13Fr products a flush adaptor to enable connection with syringes for flushing the sheath lumen. The sheaths are radiopaque for visibility under fluoroscopy.

Intended Use: The AMPLATZER TorqVue FX Delivery System is intended to provide a pathway through which devices are introduced within the chambers of the heart.

Comparison to predicate:

The AMPLATZER TorqVue FX Delivery System is substantially equivalent to the predicate devices cleared by K072313 and K083214, AMPLATZER TorqVue Delivery System (ITV) and AMPLATZER TorqVue 45°x45° Delivery Sheath (TV 45°x45°), respectively.

With the exception of the delivery cable, extension wire, and hemostasis valves, the components used in the ITV FX are identical to those used in ITV and/or TV 45°x45°.

A high-level comparison of TorqVue FX Delivery System components to the currently marketed predicate components is provided in **Table 1** below.

Table 1. TV FX Comparison to Predicates

TorqVue FX Component	Comparison to Predicate Component
Hemostasis Valves	*New (equivalent to ITV)
Flush Adapter	Identical to TV 45°x45°
Loader	Identical to ITV
Sheath	Identical to ITV and Equivalent to TV 45°x45°
Dilator	Identical to ITV and Equivalent to TV 45°x45°
Delivery Cable	*New (equivalent to ITV)
Vise	Identical to ITV
Extension Wire	*New

*Design verification testing was completed for new components, see Section 11.

The ITV FX contains a two-piece flex delivery cable assembly that incorporates a nitinol core wire surrounded by a stainless steel coil capped by a hub and a self-sealing hemostasis valve. The coil component provides rigidity for advancing devices through the sheath and then the Nitinol core wire can be extended out of the coil to provide additional flexibility for confirming correct placement of the deployed device. The stainless steel coil is equivalent to ITV, and the Nitinol core wire concept is similar to the currently marketed AMPLATZER Vascular Plug II (AVP2) delivery wire.

A 0.035" compatible extension wire will also be packaged with the ITV FX Delivery System, and will only be used for attaching to the delivery cable *in vivo* when there is a need to replace the sheath with a new sheath. The standard ITV and ITV FX dilators fit over the extension wire and delivery cable core wire. The extension wire is similar in design and materials to the AVP2 delivery wire.

The modifications have not altered the fundamental scientific technology of the predicate device.

Functional and Safety Testing:

Bench and laboratory testing was performed to support a determination of substantial equivalence to the predicate device. Results from testing of the proposed and predicate devices show the proposed device conforms to the requirements for its intended use. Testing performed on the proposed device (ITV FX Delivery Cable and Extension Wire) included the following:

- Delivery Cable and Extension Wire Dimensional Tests
- Delivery Cable Vacuum Decay
- Extension Wire Connection Reliability
- Delivery Cable Core Wire Distal Tip Flexibility
- Delivery Cable and Extension Wire Corrosion Testing
- Delivery Cable Distal Torque to Failure
- Delivery Cable Force Transmission
- Delivery Cable Distal Core Tensile
- Delivery Cable Core to Extension Wire Tensile
- Delivery Cable Hub to Coil Tensile
- Design Validation Testing (animal study)
- Device Interaction Testing
    - Advancement/Deployment Test
    - Recapture Test
    - Visual Inspection Post-Interaction Testing
- Hemostasis Valve Leak Testing

Testing performed on the predicate devices (ITV Sheath and Dilator, TV 45°x45°) and leveraged for ITV FX included the following:

- Sheath Surface Inspection
- Dilator Surface Inspection
- Sheath Tip Tensile Test
- Dilator Hub Tensile Test
- Sheath Hub Tensile Test
- Loader Distal Luer Tensile
- Loader Hub Tensile
- Sheath Luer Leak Test (water and air)
- Flush Adaptor Luer Leak
- Sheath Torque to Failure

Conclusion:

AGA Medical Corporation considers the AMPLATZER TorqVue FX Delivery Systems to be substantially equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

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Re: K121611
Trade/Device Name: Amplatzer TorqVue FX Delivery System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 19, 2012
Received: July 20, 2012

Dear Ms. Kollmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K121611

Device Name: AMPLATZER® TorqVue FX Delivery Systems

Indications for Use: The AMPLATZER® TorqVue FX Delivery System is intended to provide a pathway through which devices are introduced within the chambers of the heart.

Prescription Use X **(Part 21 CFR 801 Subpart D)**	**AND/OR**	**Over-The-Counter Use** _____ **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121611